SIEMENS

SIREMOBIL Iso-C

SP

Maintenance Instructions

System

SIREMOBIL Iso-C

The protocol SPR2-230.105.02.06.02 is required for these instructions

© Siemens AG 1998

The reproduction, transmission or use of this document or its contents is not permitted without express written authority. Offenders will be liable for damages. All rights, including rights created by patent grant or registration of a utility model or design, are reserved.

English

Doc. Gen. Date: 07.05

Print No.: SPR2-230.101.02.06.02 Replaces: SPR2-230.101.02.05.02

Document revision level

The document corresponds to the version/revision level effective at the time of system delivery. Revisions to hardcopy documentation are not automatically distributed.

Please contact your local Siemens office to order current revision levels.

Disclaimer

The installation and service of equipment described herein is to be performed by qualified personnel who are employed by Siemens or one of its affiliates or who are otherwise authorized by Siemens or one of its affiliates to provide such services.

Assemblers and other persons who are not employed by or otherwise directly affiliated with or authorized by Siemens or one of its affiliates are directed to contact one of the local offices of Siemens or one of its affiliates before attempting installation or service procedures.

Table of Contents

1	General Information	_ 5
	Prerequisites	. 5
	Required documents	. 6
	Systems equipped with SIMOMED N X 2080 monitor	
	Systems equipped with the standard 100/120Hz monitor	
	Systems equipped with TFT displays	
	Systems equipped with an I.I. laser light localizer	. 6
	Systems equipped with a laser light localizer	
	Systems equipped with DICOM bridge	
	Systems equipped with Codonics printer	. 7
	Required tools, measurement and auxiliary devices	
	Spare parts which may be needed	10
	Notes and symbols	11
	Safety information and protective measures	12
	General safety information (in existing documents)	
	General electrical safety information	
	Radiation safety information	13
	Mechanical safety information	13
	Safety information - risk of infection	
	Laser light localizer option	15
	Information on the protective conductor resistance test	
	Explanation of symbols	20
	Explanation of abbreviations in the maintenance certificate	
	Maintenance interval	21
	Maintenance interval, system	
	Maintenance interval, 3D reconstruction combined with navigation system	21
	Technical Safety Checks (TSC)	22
2	Inspection of Exterior and Surroundings	27
	Visual inspection of exterior	07
	·	
	Inspection of environment	
	Power outlets	28
3	Safety Inspection	29
	Mechanical safety	29
	I.I. laser light localizer	
	Laser light localizer	
	DICOM bridge	
	Codonics printer	
	Navigation system	
	Monitor(s)/displays	
	Labels	31
	Electrical safety	32
	•	

	Monitor(s)/displays	33
	Operation	34
	3D reconstruction	35
	Conductive rubber	36
	Measurements	37
4	Maintenance, Operating Value / Functional Inspection	38
	Maintenance	38
	Operating value inspection	40
	Functional inspection	41
5	Final Result / Quality Inspection and General Maintenance	44
	Final Work Steps	45
6	Changes to Previous Version	46

1 General Information

1.1 Prerequisites

The prerequisites described in Chapter 1 of the Service Instructions also apply to the maintenance described in this document.

NOTE

If the system is equipped with 3D reconstruction, in combination with a navigation system, the required maintenance has to be performed together with a navigation system engineer.

1.2 **Required documents**

Safety information according to ARTD, part 2

Service protocol SPR2-230.105.02... Service instructions SPR2-230.061.01..

Image quality quick test SPR2-230.037.01...

Technical Safety Checks - Protocol* SP00-000.834.01...

1.2.1 Systems equipped with SIMOMED N X 2080 monitor

Maintenance check list Z35

Adjustment Instructions RX52-060.061.02...

1.2.2 Systems equipped with the standard 100/120Hz monitor

(SPR2-230.101.01 / Mon-Maintenance instructions

itor 44 cm, 100/120 Hz)

Service protocol (SPR2-230.105.01 / Mon-

itor 44cm, 100/120HZ)

1.2.3 Systems equipped with TFT displays

• Replacement instructions of the TFT display available.

1.2.4 Systems equipped with an I.I. laser light localizer

Installation and Setting Instructions RXR2-130.033.03

1.2.5 Systems equipped with a laser light localizer

Setting Instructions SPR2-230.032.01...

^{*} Within the purview of DIN VDE 0751-1, we recommend documenting the results of the maintenance both in the maintenance protocol and in the TSC protocol. The protocols should be filled out completely and handed over to the client after maintenance is complete.

1.2.6 Systems equipped with DICOM bridge

DICOM Bridge Installation and Setting Instructions

SPR2-130.033.04

1.2.7 Systems equipped with Codonics printer

Codonics printer EP 1660 Installation and Setting Instructions

SPR2-130.814.01

1.3 Required tools, measurement and auxiliary devices

NOTE

The indicated items are listed in the STC (Service Tools Catalog) unless otherwise stated (the STC is a component of the Spare Parts Catalog) with the exception of items marked with "*".

Tool		For example	Material no.:
•	Standard tool kit*		
•	Set of Allen wrenches*		
•	Spring balance rated for up to 200 N		44 15 113 RH090
•	Leakage current measuring device	Safety tester Unimet 1100	51 38 727
•	Protective conductor meter	Safety tester Unimet 1100	51 38 727
•	Internal line resistance meter		84 28 104 Y4337
•	DVM	Fluke 187	99 94 831
•	Luminance meter	e.g., SPOTMETER for SMfit ACT	77 52 848
•	Densitometer (if MULTISPOT 2000 option is available)		97 02 416 Y1996
•	Dose meter	PTW Diados	97 17 612 Y0388
•	Dynamic test kit		37 90 156 X1963
•	Precision X-ray filter		99 00 598 XE999
•	Set of resolution tests		28 71 820 RE999
•	Set of radiation filters (10 x 0.3 mm)		44 06 120 RV090
•	Set of radiation filters		97 98 596 G5321
•	25 mm AL measuring stand, type 26	765 acc. to DIN 6868 Part 50*	
	or		
	1.2 mm Cu (e.g., from set of radiation	n filters 44 06 120) plus	
•	17 Micrometer Cu strip		11 67 662
•	Centering cross (only with Diamentor)		96 60 051 RE999
•	Calibration phantom (if 3D reconstruction option is available)		75 51 620 G5486
•	Service PC		
•	Cable for connecting service PC to host		99 00 440 RE999

Tool		For example	Material no.:
•	Service software*	(see logbook)	
•	Sealing compound		34 43 009
•	Special oil (Optimol Optipit)		55 07 525
•	Special oil (Slic Pac PTFE)		55 07 517

1.4 Spare parts which may be needed

- Cable deflector steering castor large/SIREMOBIL stand
- Cable deflector wheels small/SIREMOBIL stand
- Conductive rubber/SIREMOBIL stand and monitor trolley

• Touch-up paint 34 44 403

• Spray paint 84 27 734 RH999

1.5 Notes and symbols

Text emphasized in technical documentation has the following meaning:

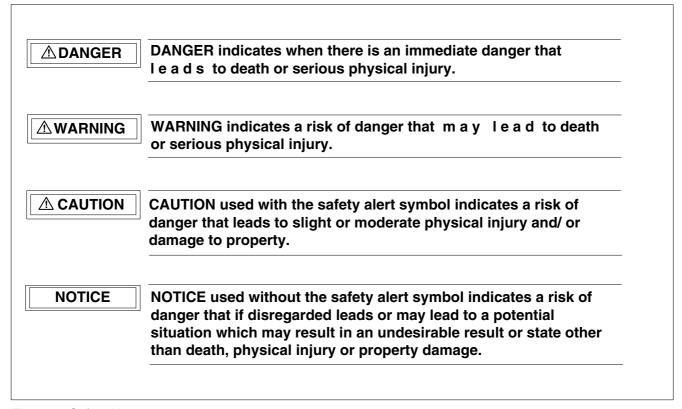


Fig. 1: Safety Notes

1.6 Safety information and protective measures

1.6.1 General safety information (in existing documents)

∆WARNING

Danger of injuries, death or material damage. Note

- the product-specific safety notes in these instructions,
- the general safety information in TD00-000.860.01... and
- the safety information in accordance with ARTD part 2.
- □ Non-compliance can lead to death, injury or material damage.

1.6.2 General electrical safety information

∆WARNING

Electrical safety!

Non-compliance can lead to severe injury or even death and material damage.

- After opening the cover panels, the parts under voltage are accessible. To avoid danger, disconnect the system from the power supply prior to opening the covers. Pull out the power supply plug.
- If an uninterruptible power supply (UPS) is installed in the system, the voltage output of the UPS must also be deenergized or the voltage output plug must be disconnected.
- If work has to be performed under electrical voltage, the general safety information according to TD00-000.860.01... must be complied with.

∆CAUTION

Electrical voltage!

Non-compliance can result in material damage.

□ When working on the system, ESD regulations must be observed.

1.6.3 Radiation safety information

⚠WARNING

X-ray radiation!

Non-compliance can lead to illness, irreversible damage to body cells and the genotype, severe injury and even death.

When performing work on the system during which radiation must be released, the radiation protection directives and the rules for radiation protection according to ARTD 02.731.02 must be complied with.

- □ Use available radiation protection devices.
- ⇔ Wear radiation protection clothing (lead apron).
- ⇔ Stay as far away as possible from the radiation source.
- □ Set the radiation activity as low as possible. (low kV and mA values, short radiation time)
- □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
 □
- □ Checks in which radiation must be released are identified by the radiation warning symbol.

1.6.4 Mechanical safety information

∆CAUTION

Risk of burns from hot parts or components! If not observed, minor to more severe burns, especially on the hands, can occur.

Parts and components (e.g., power components, cooling fins, electromagnetic brakes) that can exceed 50 degrees Celsius during operation are accessible after the covers are opened.

□ To avoid burns, switch the system off prior to touching parts or components and allow at least 5 minutes of cooling.

∆WARNING

Risk of injury from mechanical parts! If not observed, minor to more severe injury, especially to the hands, can occur.

The C-arm of the system is manufactured from carbon fiber composite material (CFK). In the case of damage to the carbon fiber structure, for example caused by collision or by cutting or scraping tools, individual carbon fibers or carbon fiber bundles can stand out and on contact cause injuries to the skin or penetrate into the tissue of the hand.

- □⇒ Before starting work on the C-arm, make sure that there is no damage to the carbon fiber structures (visual inspection).
- □→ If smaller superficial damage is detectable in the painted area or in the area of the running surface edges of the C-arm, wear working gloves and remove any projecting carbon fibers. Then carefully rub the damaged places flat with a fine emery cloth and close the damaged surface with paint. A spray paint in the color of the C-arm can be used for this purpose (see the Service Tool Catalog). Remove any carbon fibers lying in the C-arm profile with a damp sponge or cloth.
- □→ If greater damage to the carbon fiber structure indicating general or large-scale destruction of the carbon fiber structure (e.g., crack formation or flaked-off places on the running surfaces with torn carbon fibers) can be detected, replace the C-arm.

∆CAUTION

Risk of injury from mechanical parts! If not observed, minor to more severe injury, especially to the hands, can occur.

Parts such as flat plugs, threaded bolts, cut-off cable ties and component edges that, if care is not taken, can cause crushing, abrasion and cuts to the skin, particularly to the hands, can be touched after the covers are opened.

- □ Perform the required work with special care and attention to detail.
- If needed, wear working gloves.

1.6.5 Safety information - risk of infection

∆WARNING

Risk of infection due to pathogens! Non-compliance can lead to severe injury and even death.

This product can be contaminated by infected blood or other bodily fluids.

- Avoid all contact with blood or other bodily fluids!
- ⇔ Strictly observe the safety information in ARTD-002.731.37... regarding prevention of infectious diseases during customer service calls.

1.6.6 Laser light localizer option

NOTICE

Laser emissions!

Non-compliance can result in injury, in particular to the retina, and consequently in irreversible sight damage.

This product contains class 2 lasers.

(USA: class 2 laser).

□⇒ Observe the safety information in ARTD-002.731.03. Do not look directly into the laser beam when using the laser light localizer.

NOTE

The eye is not in immediate danger.

(blinking reflex of the eye).

Nevertheless do not look directly into the laser beam.

1.7 Information on the protective conductor resistance test

Observe the instructions in the safety rules for installation and repair (ARTD-002.731.17 ...).

The protective conductor resistance is to be measured, documented, and evaluated during maintenance.

NOTE

Evaluate the results by comparing the first measured value to the corresponding values documented during preceding maintenance procedures or safety checks.

A sudden or unexpected increase in the measured values may indicate a defect in the protective conductor connections - even if the limit value of 0.2 ohms is not exceeded.

(Protective conductor or contacts).

The measurement must be performed according to DIN VDE 0751, part 1 (see ARTD part 2). In this case the protective conductor resistance for all touchable conductive parts must be measured during the normal operating state of the system.

Make sure that control cables or data cables between the components of the system are not mistaken for a protective conductor connection.

During the measurement the power cable and additional connection cables which also make the ground wire connection between parts of the system (e.g., monitor cable between C-arm chassis and monitor trolley) must be moved section by section to detect broken conductors.

The protective conductor resistance must not exceed 0.2 Ohms.

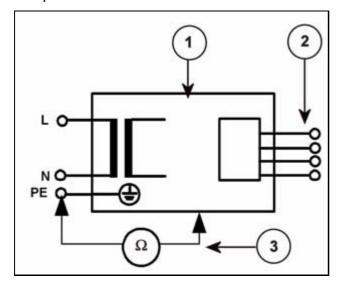


Fig. 2: Measuring circuit for measuring the protective conductor resistance in units/systems that are permanently connected to the power supply net (according to DIN VDE 0751-1:2001-10, Fig. C3).

Pos. 1 System

Pos. 2 Application part (not available)

Pos. 3 Measurement setup (integrated into measuring device)

The determined values, including the measuring points, must be recorded and assessed in the protective conductor resistance protocol.

The measuring procedure and the measuring device used (designation and serial number) are also to be documented.

1.7.1 Information on measuring the system leakage current

NOTE

The system leakage current measurement is to be conducted and recorded as the repeat measurement during maintenance.

However, the first measured value must be newly determined and a new report must created under the following conditions:

Lack of system leakage current measurement documentation

Local line voltage or line frequency deviating from the line voltage and line frequency documented in the report (e.g., in the event of a site/operator change)

Use of a different procedure for measuring the system leakage current from the one documented in the report.

For the purpose of traceability, reference to the new protocol is to be written on the old protocol. The reason for newly determining the first measured value is to be documented and confirmed with a name and signature.

Observe the instructions in the safety rules for installation and repair (ARTD-002.731.17 ...).



Electrical voltage!

Non-compliance can lead to severe injuries and even death.

The system leakage current measurement may be performed on systems of protection class I only after the protective conductor test has been passed.

First measured value

The first measured value was already determined and documented in the system leakage current report. The measuring procedure was also recorded.

The measurement was performed with the recorded line voltage, line frequency and with the recorded measuring equipment.

Measurement

Perform the measurement according to DIN VDE 0751, part 1 (see ARTD-002.731.17....), and record the determined value.

The measuring procedure indicated in the report must be used.

If the first measured value has to be newly determined (see note), a measuring procedure can be selected (direct measurement or differential measurement).

Measurement of the system leakage current according to the differential current method (measurement setup according to (Fig. 3 / p. 18)) must be given preference, since this method is not dangerous to the person performing the measurement and other persons.

However, please note the minimum resolution of the leakage current measuring instrument and any additional manufacturer's data restricting the use of the measuring device.

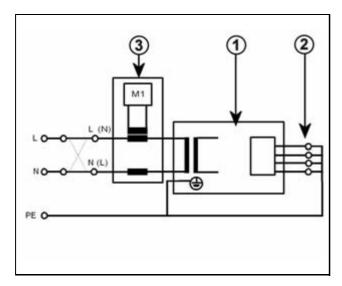


Fig. 3: Measuring circuit for measuring the system leakage current according to the differential current method in compliance with DIN VDE 0751-1:2001-10, Fig. C6 for protection class I.

Pos. 1 System

Pos. 2 Application part (not available)

Pos. 3 Measurement setup (integrated into measuring device)

If the direct measurement of the system leakage current is used (measurement setup according to (Fig. 4 / p. 18)), the system must be insulated during the measurement and must not be touched.

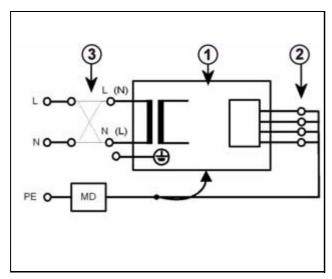


Fig. 4: Measuring circuit for direct measurement of the system leakage current in compliance with DIN VDE 0751-1:2001-10, Fig. C5 for protection class I.

Pos. 1 System

Pos. 2 Application part (not available)

Pos. 3 Measurement setup (integrated into measuring device)



Electrical voltage!

Non-compliance can lead to severe injuries and even death. No housing parts of the system may be touched during direct measurement of the leakage current (Fig. 4 / p. 18).

Third-person access to the system must be prevented.

The system must be switched on during measurement. Measuring devices with automated measuring sequences must therefore be set to manual measurement.

The highest value must be entered in the leakage current report.

This value must not exceed the permissible leakage current values according to DIN VDE 0751-1:2001-10, table F.1, line "System leakage current for devices according to remarks 1 and 3", of 2.5 mA.

Measure and record the current line voltage. If the measured line voltage deviates from the nominal voltage, correct the measured value to the value corresponding to a measurement at the nominal value of the line voltage. This is also to be documented.

Document the measuring procedure (differential measurement or direct measurement) and the measuring device used (designation and serial number).

In the case of repeat measurements, the measured value must also be evaluated.

NOTE

Evaluate the results by comparing the first measured value to the corresponding values documented during preceding maintenance procedures or safety checks.

A sudden or unexpected increase of the measured values may indicate that a fault has occurred in the primary circuit of the power supply (damaged insulation, damage caused by water ingress or humidity, defective interference suppressor, etc.) - even if the limit value of 2.5 mA is not exceeded.

The evaluation is not necessary in the case of a new determination.

File the report sheet in the system folder or log book.

1.8 Explanation of symbols

1.8.1 Explanation of abbreviations in the maintenance certificate

Abbrev.	Description
SI	Safety Inspection
SIE	Electrical Safety
SIM	Mechanical Safety
PM	Preventive Maintenance
PMP	Periodic Preventive Maintenance
PMA	Preventive Maintenance Adjustments
PMF	Preventive Check of Operating Values/Functions
Q	System Quality, Image Quality
QIQ	Image Quality
QSQ	System Quality Check
SW	Software Maintenance
CSE	Customer Service Engineer
KSK No.	Customer-specific code
IVK	Installed Volume Component
GR	Maintenance Unit

The steps identified by these abbreviations are part of the maintenance certificate and should be checked off upon completion.

1.9 Maintenance interval

1.9.1 Maintenance interval, system

NOTE

The maintenance interval applies to all maintenance work, except for the maintenance of the 3D reconstruction in combination with a navigation system.

• 12 months

1.9.2 Maintenance interval, 3D reconstruction combined with navigation system

NOTE

If the system is equipped with the 3D reconstruction option in combination with a navigation system, perform the maintenance work listed below in the specified maintenance interval.

NOTE

Take into account that the maintenance work listed below has to be performed together with an engineer of the navigation system manufacturer.

- SIM Navigation system (if present)
 - I.I. ring damage

Correction of the seating of the I.I. cap

- SIE 3D reconstruction (if present)
 - Calibration of 3D reconstruction
 - Check of the limiting resolution
- SIE 3D reconstruction with navigation system (if present)
 Check the overall navigation accuracy
- 6 months, however after 150 patients (approx. 300 3D scans) at the latest.

1.10 Technical Safety Checks (TSC)

Abbreviation: TSC = Technical Safety Checks

NOTE

- Within the purview of DIN VDE 0751-1, the operator of medical engineering products has to perform technical safety checks at regular intervals.
- The checks listed in these maintenance instructions contain all technical safety checks according to DIN VDE 0751-1 except for the check of the completeness, presence and legibility of the necessary operator documents.
- A separate report with print number SP00.000.834.01... is available for each technical safety check.
- Within the purview of DIN VDE 0751-1, we recommend documenting the maintenance results both in the maintenance report and in the TSC report. The reports should be filled out completely and handed over to the client after maintenance is complete.
- The table below assigns each technical safety check listed in document SP00.000.834.01... to the corresponding maintenance work.

Technical safety checks, test certificate of the check	Maintenance instructions for the check/comments
1 Identification data	Please fill in the fields.
2 General checks	n.a.
2.1 Visual inspection: Is there any damage	3. Mechanical safety, checks:
affecting safety?	SIM Covers
	SIM Cable deflectors
	SIM Foot brake
	SIM Brakes
	SIM C-arm
	Emergency Stop switch
	SIM Monitors/displays
2.2 Are all cables and cable guides secure and without any visible damage?	3. Electrical safety, check:
	SIE Cables and plugs
	SIE Voltage discharge rubber

Technical safety checks, test certificate of the check	Maintenance instructions for the check/comments
2.3 Are undamaged accessories being	3. Mechanical safety, checks:
used?	SIM I.I. laser light localizer mechanics
	SIM I.I. laser light localizer function
	SIM Laser light localizer mechanics
	SIM Laser light localizer function
	SIM Navigation system
	SIM DICOM bridge mounting
	SIM Codonics printer mounting
2.4 System radiation protection devices	3. Electrical safety, checks:
present and undamaged? (No on-site radi-	SIE Fluoroscopic timer
ation shield)	SIE Audible warning signal
	SIE Compulsory radiation switch-off
	SIE Check of the radiation release switches
	SIE Dose rate
	SIE Radiation indicators
	SIE Iris collimator
	SIE Area dose product measuring unit
2.5 Are the required operator documents complete, present and legible?	Operating instructions must be available. Ask the customer for additional required operator documents and check them for completeness, availability, and legibility.
2.6 Are all warning labels in place and rec-	3. Mechanical safety, checks:
ognizable?	SIM Warning signs
	SIM ID labels
2.7 Are the operating symbols, light indica-	3. Electrical safety, check:
tors and button labels OK?	SIE Check of the operating functions
3. Electrical checks	n.a.
3.1 Measurement of protective conductor	3. Electrical safety, check:
resistance	SIE Protective conductor test
	5.1 Final work steps, check:
	SIE Protective conductor test
3.2 Leakage current or equivalent leakage current measurement	n.a.

Technical safety checks, test certificate of the check	Maintenance instructions for the check/comments
3.2.1 Leakage current measurement	3. Electrical safety, check:
	SIE Leakage current
	5.1 Final work steps, check:
	SIE Leakage current
3.2.2 Equivalent leakage current measurement	n.a.
3.3 Patient leakage current or equivalent patient leakage current measurement	n.a.
3.3.1 Patient leakage current measurement	n.a.
3.3.2 Equivalent patient leakage current measurement	n.a.
4. Mechanical checks	n.a.
4.1 Are all wall, ceiling and floor mountings	3. Mechanical safety, check:
secure and undamaged?	SIM Monitor(s) / displays
4.2 Are all mechanically moved system	3. Mechanical safety, checks:
parts clean and running smoothly (lubricated, if required)?	SIM Covers
catou, ii roquirou).	SIM C-arm
	SIM Lifting column
4.3 Are the wire cables, belts and spindles	3. Mechanical safety, checks:
free of wear and tear?	SIM Lifting column
	SIM 3D reconstruction
4.4 Mobile equipment: Are the wheels, roll-	3. Mechanical safety, checks:
ers and brakes OK?	SIM Foot brake
	SIM Brakes SIM Wheels
4.5 Is there any unusual noise during oper-	3. Mechanical safety, checks:
ation (e.g., gearing)?	SIM C-arm
	SIM Lifting column
5. Functional checks	n.a.
5.1 Function of the Emergency Stop switch	3. Mechanical safety, check:Emergency Stop switch3. Electrical safety, check:
	SIE 3D reconstruction

Technical safety checks, test certificate of the check	Maintenance instructions for the check/comments
5.2 Are the warning devices functioning	3. Electrical safety, checks:
properly?	SIE Audible warning signal
	SIE Radiation indicators
5.3. Do all system movements stop prop-	3. Mechanical safety, check:
erly in their end positions?	SIM Lifting column
	3. Electrical safety, check:
	SIE 3D reconstruction
stop all system movements properly (e.g.,	Check the collision protection, if it is installed.
	Otherwise: n.a.
5.5. Are all safety distances (wall, floor,	Check the measures if they are installed:
ceiling) met or ensured by other appropriate measures (such as light barriers)?	Otherwise: n.a.
5.6. Are the other safety shutdown devices	Check the measures if they are installed:
functioning properly (e.g., safety floor plate)?	Otherwise: n.a.
5.7 Are the positions of the table and system reproducible (e.g., zero positions, layer height, etc.)?	n.a.

Technical safety checks, test certificate of the check	Maintenance instructions for the check/comments
6. Product-specific checks	3. Electrical safety, checks:
	SIE 3D reconstruction
	SIE 3D reconstruction in combination with a navigation system
	SIE IQ quick test
	SIM DICOM bridge IQ test
	SIM Codonics printer IQ test
7. Test result/evaluation:	Evaluate the long-term trends of the protective conductor resistance and the leakage current by comparing the current measuring values to those of the preceding technical safety checks. A sudden or unexpected increase in the measured values may indicate a safety-related defect - even if the limit values are not exceeded. Follow the instructions for checks in the section on final work steps.
	Enter the results of the check.
	Have the operator, or a person authorized by the operator, sign the TSC report.
	Hand the TSC report over to the operator, or a person authorized by the operator.

2 Inspection of Exterior and Surroundings

2.1 Visual inspection of exterior

PMP Damage to the system

• Inspect the entire system for damage, such as damage to the housing or paint.

PMP Damage to the mains connection

• Check power lines, plugs, socket panels and outlets for damage.

2.2 Inspection of environment

2.2.1 Power outlets

SIE Damage

Inspect the power outlets used for system operation for damage.

SIE Mains voltage

• Measure the line voltage and compare it to the line voltage label on the monitor trolley.

SIE Internal line impedance

• Measure the internal line impedance.

3 Safety Inspection

3.1 Mechanical safety

SIM Cover panels

- Remove the covers from the SIREMOBIL stand and monitor trolley.
- Check cover panels for damage.

SIM Cable deflectors

• Inspect the cable deflectors on the stand and on the monitor trolley.

SIM Foot brake

 Test the function of the foot brakes on the SIREMOBIL stand and monitor trolley on a level floor.

SIM Brakes

 Use the spring balance to test whether the orbital, angulation, swivel and horizontal movement brakes apply the prescribed force. (Refer to service instructions SIREMO-BIL ISO-C)

SIM C-arm

- Check the C-arm for damage to the carbon fiber structures (visual inspection). If there is damage, proceed as described in the warning in chapter 1.
- Perform all C-arm movements, checking for slackness of the bearings and bearing noises.
- Orbital movement: Once the orbital brake is released, the C-arm can be moved only in a limited manner. Check whether the orbital movement is smooth.

SIM Wheels

- Move the SIREMOBIL in a straight line on a level floor.
- Evaluate the straight and quiet movement of the SIREMOBIL.
- Replace any defective wheels or castors.
- Check the steering function.

SIM Lifting column

- Switch the system on
- Electrically raise and lower the lifting column,
 - while listening for noises and checking for play in the bearings.
 - The lifting column movement must switch off automatically when the end positions are reached.
- Switch off the system.
- Lubricate the lifting column.
 - Lubricate the bearing surfaces of the lifting column guide and the spindle.

SIM Emergency Stop switch

- Press the Emergency Stop switch. The lifting column may not be raised or lowered.
- Press the Emergency Stop switch again. The lifting column can be moved again.

3.1.1 I.I. laser light localizer

SIM Mechanical system

- Inspect the I.I. laser light localizer for mechanical damage.
- Mount the I.I. laser light localizer on the I.I. and ensure proper locking and seating. When doing this, pay special attention to the tension band and its closure.
- Check the I.I. ring for damage.

SIM Function

Perform maintenance on the I.I. laser light localizer according to Installation and Setting Instructions RXR2-130.033.03...

3.1.2 Laser light localizer

SIM Mechanical system

- Inspect the I.I. cap of the laser light localizer for mechanical damage.
- Install the I.I. cap of the laser light localizer on the I.I. and ensure proper locking and seating.
- Check the I.I. ring for damage.

SIM Function

 Perform the maintenance steps specified according to the adjustment instructions SPR2-230.032.01..

3.1.3 DICOM bridge

SIM Mounting

Check the mounting of the DICOM bridge in the monitor trolley.

3.1.4 Codonics printer

SIM Mounting

- Inspect the screws used to fasten guide rail to the mounting bracket of the Framegrabber
- Ensure that the printer is properly fastened to the guide rail. Make sure there are no missing attachment screws.
- Ensure that the Framegrabber is properly fastened to the mounting bracket. Make sure there are no missing attachment screws.

SIM Guide rails

- Inspect the guide rails for proper function and smooth operation.
- The guide rails must not be damaged.
- The guide rails must lock properly into place when fully pushed into position.
- If necessary, use a cleaning brush to remove dirt from the rails.

3.1.5 Navigation system

SIM Navigation system

- Check the I.I. ring for damage.
- Install the I.I. cap of the navigation system and ensure proper locking and seating.

3.1.6 Monitor(s)/displays

SIM Monitor(s)/displays

- Check the monitor(s) and/or displays for damage.
- Ensure that the monitor(s) or displays are correctly mounted to the monitor trolley.

3.1.7 Labels

SIM Warning signs

- Ensure that all required warning labels are attached and in good condition.
 - Replace any illegible labels or markings.

SIM ID labels

- Ensure that all required ID labels are attached and in good condition.
 - Replace any illegible labels or markings.

3.2 Electrical safety

SIE Cables and plugs

• Check visible system cables and plugs for damage.

SIE Fluoroscopic timer

Check: See section on "Compulsory radiation switch off".

SIE Audible warning signal

Check: See section on "Compulsory radiation switch off".

SIE Radiation indicators

Check: See section on "Compulsory radiation switch off".

SIE Radiation release switch

Check: See section on "Compulsory radiation switch off".

SIE Compulsory radiation switch off

Test the functioning of the audible warning signal and compulsory radiation switch off (if required) according to the country-specific regulations. Also perform the following checks:



- Release fluoroscopy for one minute. Use a wristwatch to check the proper functioning of the fluoroscopic timer.
- All radiation indicators on the system operating console and monitor trolley must illuminate during fluoroscopy release.



- Check the function of the radiation release switches (hand and foot switches).
- Check the radiation release switches for damage.
- Check the cables of the hand and foot switches for mechanical damage.
- Move the cables of the hand and foot switches to check for breaks and short circuits.

NOTE

- Depending on the programming, the audible warning signal has to sound 4.5, 5 or 9.5 minutes after the fluoroscopy has started. It sounds again every 5 or 10 minutes. It is turned off by pressing the -0- button once.
- Pressing this button again resets the fluoroscopic timer to "0".
- Depending on the country-specific programming, either the required radiation shut off does not occur or it occurs every 5 or 10 minutes and then every 5 or 10 minutes after that.

SIE Dose rate



- Switch the system on
- Check the dose rate (refer to the service instructions for SIREMOBIL ISO-C).

SIE Iris collimator



- Check the iris collimator and correct it if necessary.
 - Select the full I.I. format and release fluoroscopy briefly.
 - The collimator blades must be clearly visible at the edges of the image.
 - Select a zoom format and release fluoroscopy briefly.
 - The collimator blades must be clearly visible at the edges of the image.

SIE Area-dose product measuring device



- Check the area-dose product measuring device
- (refer to the service instructions for SIREMOBIL ISO-C).

SIE Codonics printer cable break

 Inspect all connection lines between the printer and the Framegrabber for damage and breaks. Inspect the cable routing of the energy chain for damage and proper functionality (ensure that none of the cables are pinched).

3.2.1 Monitor(s)/displays

SIE Monitor(s)/displays

- Check the SIMOMED N monitors as prescribed in the checklist.
- Check the luminance of the standard monitors with 100/120 Hz.
- Check the luminance of the TFT displays. Check the ambient light sensor.

3.3 Operation

SIE Check the operating functions

- Check whether the operating icons and button labels are clearly legible and recognizable.
- Check whether the light indicators of the operating elements and displays are properly functioning.
- Check all system operating functions.

3.4 3D reconstruction

SIE 3D reconstruction

NOTE

The calibration of the 3D reconstruction is part of the safety inspection. It can, however, also be performed together with the IQ quick test.

See (Final Result / Quality Inspection and General Maintenance / p. 44), IQ quick test.

- Check the belt tension of the toothed belt for motor-controlled orbital movement.
- Press the Emergency Stop switch and perform a 3D scan. The motor-controlled orbital movement must not start up.



- Deactivate (disengage) the Emergency Stop switch.
- Start a further 3D scan. The 3D scan must be executed properly. The motor-controlled orbital movement must stop at the end position of the C-arm.
- Calibrate the 3D reconstruction. See section "IQ quick test".
- Check the 3D limiting resolution. See "IQ quick test".
- If the system is equipped with a navigation system, the required calibration of the 3D reconstruction has to be performed together with a navigation system engineer. Before
 starting the calibration, make sure that the I.I. cap of the navigation system is in place.
 See "IQ quick test".

SIE 3D reconstruction with navigation system

NOTE

Checking the overall accuracy of the navigation system in combination with the 3D reconstruction is part of the safety inspection. It can, however, also be performed together with the IQ quick test.

See (Final Result / Quality Inspection and General Maintenance / p. 44), IQ quick test.



Check the overall accuracy of the navigation system together with an engineer of the navigation system manufacturer. See "IQ quick test".

3.5 Conductive rubber

SIE SIREMOBIL stand voltage discharge rubber

 Inspect the voltage discharge rubber on the SIREMOBIL stand for damage or dirt. If necessary, clean or replace it.

SIE Monitor trolley voltage discharge rubber

• Inspect the voltage discharge rubber on the monitor trolley for damage or dirt. If necessary, clean or replace it.

3.6 Measurements

SIE Protective conductor test (performed under "Final Work Steps")

- Test the protective conductor with the protective conductor wire tester according to ARTD-002.731.17....
- The protective conductor resistance must not exceed 0.2 Ohms.

NOTE

The protective conductor test is part of the safety inspection. However, it cannot be performed until all maintenance work has been completed. See (Final Work Steps / p. 45).

SIE Leakage current test (performed under "Final Work Steps")

 Perform the leakage current test with the system closed according to ARTD-002.731.17. Document and evaluate the determined values. Document the measuring procedure. The leakage current must not exceed 2.5 mA.

NOTE

The leakage current test is part of the safety inspection. However, it is recommended to perform it only at the end of maintenance, with the system closed. See (Final Work Steps / p. 45).

38 Maintenance, Operating Value / Functional Inspection

4 Maintenance, Operating Value / Functional Inspection

4.1 Maintenance

PMP Cleaning the system

- Clean the entire system:
 - Visible cables
 - Exterior surfaces
 - Contact surface of wheels
 - Interior space

PMP System ventilation

• Clean the ventilation slots of the SIREMOBIL stand and monitor cart.

PMP Memoskop ventilation

- Clean the ventilation slots on the Memoskop.
- Check that the fan is functioning properly.

4.1.1 DICOM bridge

PMP Ventilation

- Clean the ventilation slots of the DICOM bridge.
- Check that the fan is functioning properly.

4.1.2 Codonics printer

PMP Ventilation

- Clean the ventilation slots of the printer and Framegrabber.
- Check that the fan is functioning properly.

PMP Cleaning

NOTE

According to the EP1660 user manual, it is the responsibility of the customer to clean the thermal print head and the mechanics for film transport. The interval between cleanings is also specified in the user manual. Refer to the maintenance chapter for the Codonics printer. The annual cleaning of the printer described here is not a substitute for regular maintenance by the customer. In the event that malfunctions occur or image quality worsens due to insufficient cleaning, please refer the customer to the maintenance activities/interval described in the Codonics user manual.

Danger of burns!

- □ Allow the thermal print head to cool off before cleaning!
- Clean the printer as described in the maintenance chapter of the Codonics user manual. Use the customer's cleaning pads (some cleaning pads are included in the delivery volume of the printer).

40 Maintenance, Operating Value / Functional Inspection

4.2 Operating value inspection

PMF Error memory

• Read out the error memory of the system and analyze the results.

4.3 Functional inspection

PMF Video printer

- Check the function of the video recorder.
- Check the remote control (Print button).

PMF Video recorder

- Check the function of the video recorder.
- Check the function of the remote control (REC-Pause-Start / REC-Pause-Stop).

PMF Laser camera system "Sneaker Net"

• Check the function of the laser-camera system "Sneaker Net".

PMF DICOM bridge

• Check the function of the DICOM bridge.

PMF DICOM Connect

• Check the function of the DICOM Connect network connection.

PMF Codonics printer manual control panel

- Check the function of the printer.
- Check the function of the manual control panel.
- Inspect the cable of the manual control panel for damage and breaks.

PMF 4 View

- Check the plug-in connections for damage.
- Check the function of the 4 View monitor extensions.
- Check the function of the additional monitors and the additional keyboard (if present).

PMF Laser camera connection

- Check the functioning of the laser camera connection.
- Check the remote control (Print button).

PMF Image rotation



- Check the image rotation (camera rotation).
 Check the 0° position and the entire rotation range (±220°) under fluoroscopy.
- Check the function of the image rotation.

PMF Slot diaphragm



- Select I.I. full format.
- Open the slot diaphragm completely and briefly release fluoroscopy.
 - The slot diaphragm plates are no longer visible on the screen.



- Select I.I. zoom format.
- Release fluoroscopy briefly.

The slot diaphragm plates are no longer visible on the edges of the image.

42 Maintenance, Operating Value / Functional Inspection



Close the slot diaphragm.

Rotate the slot diaphragm \pm 360° under fluoroscopy. The slot diaphragm can be rotated 360°.

PMF Monitor display of the iris collimator aperture

- Select I.I. full format.
- Close the iris collimator (X-iris) completely.



Mark the diameter of the collimated iris collimator aperture on the monitor.

Release fluoroscopy briefly.

The actual diameter of the iris collimator is visible.

The previously indicated monitor display of position and diameter must coincide with the actual iris collimator aperture.

- Open the iris collimator completely.
- Mark the diameter of the collimated iris collimator opening on the monitor.



Release fluoroscopy briefly.

The actual diameter of the iris collimator is visible.

The previously indicated monitor display of position and diameter must coincide with the actual iris collimator aperture.

- Select I.I. zoom format.
- Close the iris collimator (X-iris) completely.
- Mark the diameter of the collimated iris collimator aperture on the monitor.
- Release fluoroscopy briefly.

The actual diameter of the iris collimator is visible. The previously indicated monitor display must match the position and diameter of the actual iris collimator aperture.

Open the iris collimator completely.



- Mark the diameter of the collimated iris collimator opening on the monitor.
- Release fluoroscopy briefly.

The actual diameter of the iris collimator is visible.

The previously indicated monitor display must match the position and diameter of the actual iris collimator aperture.

PMF Monitor display of the slot diaphragm positions

- Select I.I. full format.
- Completely close the slot diaphragm and rotate the slot diaphragm from its basic position.
- Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.



Release fluoroscopy briefly.

The actual position (distance of the plates and angle of rotation) of the slot diaphragm is visible. The previously indicated monitor display of position and angle of rotation must coincide with the actual position of the slot diaphragm.

• Open the slot diaphragm completely and rotate it again.

Maintenance, Operating Value / Functional Inspection 43

 Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.



Release fluoroscopy briefly.

The actual position (distance of the plates and angle of rotation) of the slot diaphragm is visible. The previously indicated monitor display of position and angle of rotation must coincide with the actual position of the slot diaphragm.

- Select I.I. zoom format.
- Completely close the slot diaphragm and rotate the slot diaphragm from its basic position.
- Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.



Release fluoroscopy briefly.

The actual position (distance of the plates and angle of rotation) of the slot diaphragm is visible.

- The previously indicated monitor display of position and angle of rotation must coincide with the actual position of the slot diaphragm.
- Open the slot diaphragm completely and rotate it again.
- Mark the distance and angle of rotation of the displayed slot diaphragm position on the monitor.



Release fluoroscopy briefly.

The actual position (distance of the plates and angle of rotation) of the slot diaphragm is visible.

The previously displayed monitor display must match the position and angle of rotation of the actual slot diaphragm position.

NOTE

Perform this check with the lowest possible kV values so that the front edges of the slot diaphragm plate are effectively visualized.

44 Final Result / Quality Inspection and General Mainte-

5 Final Result / Quality Inspection and General Maintenance

SIE Image quality (IQ) quick test

 Perform the IQ quick test according to the SIREMOBIL ISO-C image quality quick test specifications.



• Include additional monitors and displays in the test.

SIE DICOM bridge IQ test

• Perform the IQ test according to chapter 6 of the Installation and Setting Instructions SPR2-130.033.04.. in the course of the system IQ test.

SIE Codonics printer IQ test

 Inspect the image quality according to the chapter "Testing the image quality" in the installation instructions SPR2-130.814.01...

PMP Maintenance

• Entire system: Touch up any paint damage as needed.

Final Result / Quality Inspection and General Maintenance

5.1 Final Work Steps

SIE Protective conductor test

SIE Protective conductor resistance

 Perform the protective conductor test with the system closed according to ARTD-002.731.17. Document and evaluate the determined values. The protective conductor resistance must not exceed 0.2 Ohms.

NOTE

Evaluate the results by comparing the first measured value to the corresponding values documented during preceding maintenance procedures or safety checks.

A sudden or unexpected increase in the measured values may indicate a defect in the ground wire connections (ground wire or contacts) - even if the limit value of 0.2 Ohms is not exceeded.

SIE Leakage current

 Measure the leakage current according to ARTD-002.731.17. Document and evaluate the determined values. The limit value of 2.5 mA may not be exceeded.

NOTE

Evaluate the results by comparing the first measured value to the corresponding values documented during preceding maintenance procedures or safety checks.

A sudden or unexpected increase of the measured values may indicate that a fault has occurred in the primary circuit of the power supply (damaged insulation, damage caused by water ingress or humidity, defective interference suppressor, etc.) - even if the limit value of 2.5 mA is not exceeded.

6 Changes to Previous Version

Document was converted to DMS